

### REMARKS

Reconsideration is courteously requested.

It is respectfully submitted that, in connection to claims 30-46, continued reliance upon Engel et al. is misplaced. Moreover, rationale offered in support of the rejection and/or in rebuttal to Applicant's arguments either misses the mark, or is premised upon a strained interpretation of the teaching Engel et al.

At p. 5 of the Action, namely ¶11, the following is provided:

Regarding (a)...Engel et al discloses a lower urinary tract diagnostic system and methods of use thereof capable of sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event via a pressure releasing valve and associated indwelling structure associated therewith.

First, in absolutely no uncertain terms does Engel et al. disclose "a lower urinary tract diagnostic system and methods of use thereof." Engel et al. instead disclose a valved urinary catheter; nothing more, nothing less.

Second, it is admitted that the Engel et al. do not teach "sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event" (claim 30), vis-a-vis the rationale that Engel et al. is "capable of..." This rationale does not and cannot support the stated and reasserted 35 USC §102 rejection.

Third, the allegation of the Engel et al. capability being premised upon a "pressure releasing valve and associated indwelling structure associated therewith" is bogus. There is no relationship

whatsoever between a supported/unsupported condition of the prostatic urethra and Engel et al.'s pressure relief valve, let alone "pressure releasing valve and associated indwelling structure associated therewith." As is amply supported at 11:58-12:19 and FIGS. 3 & 5, closed valve 16 (FIG. 3) is "opened" (FIG. 5) by hydraulically actuation, more particularly, via user application of pressure to balloon 11 which transmits the applied pressure to semi-balloon 15 which results in opening of valve 16. Voiding via the Engel et al. device has nothing to do with physiology of the lower urinary tract, let alone the prostatic urethra.

At p. 6 of the Action, namely ¶12, the following is provided:

Regarding (b)...Engel et al discloses a lower urinary tract diagnostic system and methods of use thereof including the insertion, manipulating, and extraction of a portion of the indwelling device to permit a prostate to physiologically act upon a prostatic responsive segment of the indwelling device (e.g., the pressure responsive balloon);

with the following assertion provided at p. 2, ¶3:

- positioning and supporting a prostatic urethra via catheter (43) having balloons (4, 5, and 27) (column 11 line 43-column 12 line 18) by providing a diagnostic assembly comprising an elongate support member (as best seen in Figures 6-9) reversibly receiveable within and for selectively supporting a prostatic urethra;

With reference to, as suggested, FIGS. 6-9, there is shown: a male incontinence device (FIG. 6); a female incontinence device (FIG. 7); the device of FIG. 6 in combination with an "insertion rod 43" (FIG. 8); and, disconnect details between the rod and device (FIG. 9). There is no explicit or implicit teaching of

select support of the prostatic urethra; to the contrary, as is amply supported (8:61-9:9, and FIGS. 1, 8 & 9), a "rigid nucleus 50" within rod 43 (FIG. 9) extends through device part 2 and into device part 1 within the penile urethra, not the prostatic urethra, for the purpose of stabilizing the union of the two parts. As a matter of fact, as clearly shown in FIG. 9 (broken line/hidden view), the free end of the rigid nucleus at best underlies a portion of the device proximal (i.e., downstream) of actuator balloon 11, with any such insertion clearly intended to be limited as evidenced by the contemplated interference fit (i.e., cooperative mechanical engagement) between the insertion rod and device (see e.g., broken alignment lines of either of FIGS. 1 or 9). Without a teaching or suggestion of prostatic support, there can be no step of incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event. Further still, and as previously asserted and reiterated here for the record, Applicant's requirement of sequentially and incrementally returning portions of the prostatic urethra to an unsupported condition during a bladder voiding event (claim 30), and/or manipulating a portion of said indwelling device so as to permit a prostate to physiologically act upon a prostatic responsive segment of said indwelling device (claim 34) fly in the face of Engel et al. wherein lumen patency is critical to the functionality of a catheter, especially a valved catheter.

Again at p. 6 of the Action, namely ¶13, the following is provided:

Regarding (c) and in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. [citations omitted]

Applicant's point has been missed. Contrary to at least the characterization of Applicant's argument, and Applicant's argument in fact, in lieu of individual attack of the references, it is respectfully submitted that it was in fact the combination that was scrutinized. The combination of Engel et al. and McRae in fact lack one or more features of Applicant's claimed subject matter, and as such, a prima facie case of obvious under 35 USC §103 is thereby not met.

Further still at p. 6 of the Action, namely ¶14, the following is provided:

Regarding (d) and in response to applicant's arguments that there is no suggestion to combine the references...[i]n this case, [teaching/suggestion/motivation comes from the fact that] both Engel et al and McRae are concerned with lower urinary tract diagnostic system and methods of use thereof.

As in our past response, applicant vigorously and emphatically maintains that Engel et al. has nothing to do with diagnostics and everything to do with treatment; McRae has nothing to do with treatment and everything to do with diagnostics; and, with no nexus between a valved indwelling catheter, and a bladder pressure assessment methodology, there can be no suggestion or motivation to combine such disparate teachings.

Yet further still at p. 6 of the Action, namely ¶15, the following is provided:

Regarding (e) and in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the disclosure of the casting of Figures 7-9 and pages 31-36 of the Specification) are not recited in the rejected claim(s)...

Applicant's point has again been missed. Of the claims subject of final rejection, claims 33, 37 and 38 all explicitly recite obtaining a casting of the prostatic urethra. It was, and is, hardly Applicant's intent to argue limitations disclosed but not claimed; neither reference even suggests obtaining a casting of the prostatic urethra as claimed by Applicant, let alone teaches the breadth of the recitation directed thereto.

#### **New Claim**

New independent claim 47 is added. Among other things, the method claim requires provisions for a diagnostic urethral device having a physiologically responsive flexible wall segment, and an elongate support member for substantial receipt within and selective, sequential withdrawal from within a lumen of the device in furtherance of permitting physiologically action upon the physiologically responsive flexible wall segment. It is respectfully submitted that none of the references of record disclose a combination of such features, and that as such, the newly added claim is in condition for allowance.

**CONCLUSION**

For the reasons above, it is respectfully submitted that the subject case is in condition for allowance. Early reconsideration and favorable action are solicited.

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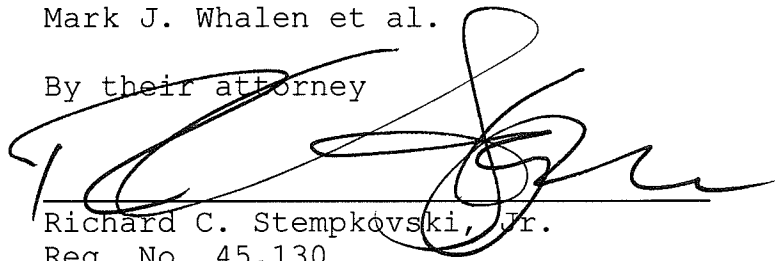
Respectfully submitted,

Mark J. Whalen et al.

By their attorney

Date

5/29/07

A large, stylized handwritten signature in black ink, likely belonging to Richard C. Stempkowski, Jr., is written over a horizontal line.

Richard C. Stempkowski, Jr.

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